

PATENT COOPERATION TREATY

REC'D 21 JUL 2005

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From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/042792

International filing date (day/month/year)
17.12.2004

Priority date (day/month/year)
17.12.2003

International Patent Classification (IPC) or both national classification and IPC
A61N1/372, A61N1/36, A61N1/08, A61N1/39

Applicant
MEDTRONIC PHYSIO-CONTROL CORP.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/042792

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/042792

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 7-19

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 7-19
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
 - the written form ☐ has not been furnished
 - ☐ does not comply with the standard
 - the computer readable form ☐ has not been furnished
 - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/042792

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-6

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-6
	No: Claims	
Inventive step (IS)	Yes: Claims	
	No: Claims	1-6
Industrial applicability (IA)	Yes: Claims	1-6
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV.

The separate groups of inventions are:

Claims 1-6 :

A patient parameter monitoring pod, comprising :
a portable housing,
a patient parameter module connectable to the patient through lead cables,
a transceiver to communicate wirelessly to a defibrillator,
and a data port to supply the patient data via a direct electrical connection to the defibrillator

Claims 7-12 :

A patient parameter monitoring pod, comprising :
a housing holding a power supply;
patient lead cables attachable between the patient and the housing,
a carrying handle positioned to protect the patient lead cable port and the patient lead cables attached to the port from direct impact.

Claims 13-19 :

A patient monitor pod system, comprising :
a portable patient monitoring pod,
a component bag,
a patient parameter module,
a data port,
wherein the component storage bag has pockets for holding the pod and components of the pod, the storage bag has openings exposing the data port and permits passage therethrough the patient lead cables.

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons: the common subject matter of the three groups of inventions is :
a patient monitoring pod, comprising :
a housing,
patient lead cables attached between a patient and the housing to collect patient data, the

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

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patient data including at least one vital sign.

These features are all disclosed in document US-A-5 105 821. For this reason, there is no unity between claims 1, 7 and 13.

Re Item V.

1 Reference is made to the following documents:

D1 : EP 1 228 782 A (ST. JUDE MEDICAL AB) 7 August 2002 (2002-08-07)

D2 : US 4 096 856 A (SMITH ET AL) 27 June 1978 (1978-06-27)

D3 : US 5 105 821 A (REYES ET AL) 21 April 1992 (1992-04-21)

D4 : EP 1 250 944 A (GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC) 23 October 2002 (2002-10-23)

2 INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of **claim 1 does not involve an inventive step** in the sense of Article 33(3)PCT.

Document D3, which is considered to represent the most relevant state of the art to the subject matter of claim 1, discloses (the references in parentheses applying to this document): a patient parameter monitoring pod, comprising:
a **portable housing** (housing of element 14, figure 1) containing a power supply;
a **patient parameter module** (element 14, figure 1) connectable to a patient via **lead cables** (leads connected to elements 39, figure 1) to collect patient data, the patient data including at least one vital sign;
and a **data port** (input connector 38, figure 1) adapted to supply the patient data via a direct electrical connection to the defibrillator (defibrillator 12, figure 1).

The subject-matter of independent claim 1 differs from the disclosure of D3 in that the patient parameter monitoring pod further comprises a **transceiver** adapted to

wirelessly transmit the patient data to a defibrillator.

The problem to be solved by the present invention may therefore be regarded as **enabling the distance-communication between the pod and the defibrillator.**

In view of D1 the solution proposed in claim 1 of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

D1 discloses the same kind of apparatus of the one described in claim 1. In D1, the patient parameter monitoring pod (element 2, figure 1) comprises a transceiver (element 8, figure 1) adapted to wirelessly transmit the patient data to a defibrillator (element 4, figure 1).

Therefore the features disclosed in D1 and D3 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (Article 33(3) PCT).

- 3 **Dependent claims 2-6** contain either features known per se from the prior art or being simple constructional features. Thus they would only satisfy Art. 33(2),(3) PCT when referring to a patentable independent claim.
- 4 In order to facilitate the examination of the conformity of the amended application with the requirements of Art. 34(2)(b) PCT, the applicant is requested to **clearly identify the amendments carried out**, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT).

If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2004/042792

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61N1/372 A61N1/36 A61N1/08 A61N1/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 228 782 A (ST. JUDE MEDICAL AB) 7 August 2002 (2002-08-07) paragraphs [0016], [0017]; claim 1; figure 1	1
Y	----- US 4 096 856 A (SMITH ET AL) 27 June 1978 (1978-06-27) column 5, line 65 - column 6, line 54; claim 1; figure 2	1
Y	----- US 5 105 821 A (REYES ET AL) 21 April 1992 (1992-04-21) column 6, line 32 - column 7, line 38; figure 1	1
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

18 March 2005

Date of mailing of the international search report

20. 07. 2005

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INTERNATIONAL SEARCH REPORT

International Application No

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 1 250 944 A (GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC) 23 October 2002 (2002-10-23)	1
A	the whole document -----	2-6
A	US 6 183 417 B1 (GEHEB FREDERICK J ET AL) 6 February 2001 (2001-02-06)	1-6
	the whole document -----	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/042792

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-6

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-6

A patient parameter monitoring pod, comprising :
a portable housing,
a patient parameter module connectable to the patient
through lead cables,
a transceiver to communicate wirelessly to a defibrillator,
and a data port to supply the patient data via a direct
electrical connection to the defibrillator

2. claims: 7-12

A patient parameter monitoring pod, comprising :
a housing holding a power supply;
patient lead cables attachable between the patient and the
housing,
a carrying handle positionned to protect the patient lead
cable port and the patient lead cables attached to the port
from direct impact.

3. claims: 13-19

A patient monitor pod system, comprising :
a portable patient monitoring pod,
a component bag,
a patient parameter module,
a data port,
wherein the component storage bag has pockets for holding
the pod and components of the pod, the storage bag has
openings exposing the data port and permits passage
therethrough the patient lead cables.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1228782 A	07-08-2002	DE 60110198 D1 EP 1228782 A1 US 2002103514 A1	25-05-2005 07-08-2002 01-08-2002
US 4096856 A	27-06-1978	NONE	
US 5105821 A	21-04-1992	US 4974600 A EP 0409591 A1 JP 3155831 A	04-12-1990 23-01-1991 03-07-1991
EP 1250944 A	23-10-2002	US 2003088275 A1 EP 1250944 A2 JP 2002360711 A	08-05-2003 23-10-2002 17-12-2002
US 6183417 B1	06-02-2001	US 5640953 A US 5685314 A AT 166734 T DE 69318850 D1 DE 69318850 T2 DK 673530 T3 EP 0673530 A1 JP 8504531 T JP 3466612 B2 WO 9414128 A2	24-06-1997 11-11-1997 15-06-1998 02-07-1998 22-10-1998 22-03-1999 27-09-1995 14-05-1996 17-11-2003 23-06-1994